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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,729	07/13/2006	Neil Cashman	P31382USA	7149

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EXAMINER	
WANG, CHANG YU	

ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,729	CASHMAN ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27 and 29-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-27 and 29-51* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-27, 29-30, 39-41, 47-51, drawn to a method for detecting whether a candidate polypeptide is in a wild-type or non-wild-type confirmation.

Group II, claim(s) 31-38, drawn to a kit for detecting whether a candidate polypeptide is in a wild-type or non-wild-type confirmation.

Group III, claim(s) 42, drawn to an isolated polypeptide of SEQ ID NO:9.

Group IV, claim(s) 43, drawn to an isolated polypeptide of SEQ ID NO:10.

Group V, claim(s) 44-45, drawn to a method of making antibody.

Group VI, claim(s) 46 (in part), drawn to an antibody against SEQ ID NO:9.

Group VII, claim(s) 46 (in part), drawn to an antibody against SEQ ID NO:10.

2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The 1st claimed invention is drawn to a method for detecting whether a candidate polypeptide is in a wild-type or non-wild-type confirmation, which is anticipated by Kim

et al. (Free Rad. Biol. Med. 2002. 32:544-550). Kim et al. disclosed a method detecting whether a-synuclein is in a wild-type or non-wild-type confirmation in the presence of Copper and H2O2 (see p. 544, abstract; p.545 materials and methods, Kim et al. (Free Rad. Biol. Med. 2002. 32:544-550), which meets the limitation of the 1st claim. Therefore, claim 1 is anticipated Kim et al. (Free Rad. Biol. Med. 2002. 32:544-550). Since the 1st claimed invention has no special technical feature, it cannot share a special technical feature with the other claimed inventions. Thus, Applicant's inventions do not contribute a special technical feature when view over the prior art, they do not have a single inventive concept and so lack unity of invention.

In addition Group I is directed to a technical feature of a method for detecting whether a candidate polypeptide is in a wild-type or non-wild-type confirmation. Group II is directed to a technical feature of a kit for detecting whether a candidate polypeptide is in a wild-type or non-wild-type confirmation. Group III is directed to a technical feature of an isolated polypeptide of SEQ ID NO:9. Group IV is directed to a technical feature of an isolated polypeptide of SEQ ID NO:10. Group V is directed to a technical feature of a method of making antibody. Group VI is directed to a technical feature of an antibody against SEQ ID NO:9. Group VII is directed to a technical feature of an antibody against SEQ ID NO:10.

Therefore, the above Inventions do not share a common special technical feature as they comprise different steps and utilize different products, which demonstrates that they have a different mode of operation and use of structurally and functionally divergent materials. Accordingly, Groups I-VII are not so linked by the same or a

corresponding special technical feature within meaning of PCT Rule 13.1 so as to form a single general inventive concept.

Species Election

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

i. If Group I is elected, Applicant is required under PCT Rule 13.2 to elect a single disclosed species of candidate polypeptide selected from A) prion, B) beta amyloid, C) tau, D) APP, E) SOD1, F) alpha-synuclein, G) huntingtin, H) p53, I) islet amyloid or J) resistin as recited in claims 2-8 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic. If SOD1 is elected, Applicant is required to further elect a single molecular embodiment of SEQ ID NO. selected from SEQ ID NOs: 5-10 as recited in claim 40 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

ii. If Group I is elected, in addition to elect the species of candidate polypeptide as set forth above, Applicant is required under PCT Rule 13.2 to further elect a single disclosed species of a corresponding disease selected from A) prion, B) BSE, C) CJD, D) Alzheimer's, E) Parkinson's, F) Lewy body, G) Huntington's, H) amyotrophic lateral sclerosis, or I) cancer as recited in claims 21-27 for

prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

iii. If Group I is elected, Applicant is required under PCT Rule 13.2 to elect a single disclosed species of blocking agent selected from A) peroxynitrite, B) hydrogen peroxide, C) methylene, D) succinic anhydride, E) epoxides, F)diethyl pyrocarbonate, G) 4-hydroxynonenal (4HNE) or H) diazirine as recite in claim 9 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

iv. If Group I or Group II is elected, Applicant is required under PCT Rule 13.2 to elect a single disclosed species of aptamer or antibody against a candidate polypeptide selected from A) prion, B) beta amyloid, C) tau, D) APP, E) SOD1, F) alpha-synuclein, G) huntingtin, H) p53, I) islet amyloid or J) resistin as recited in claims 16-19 and 33 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 31 are generic.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The technical features of these species are different because each specific species differs with respect to its composition and structures.

Consequently the responses to different biomolecules are also different in different types of cells. In addition, for the disease, the etiology and potential molecular mechanisms underlying different diseases are different. For example, the pathology and etiologies of prion diseases are very different from those of Alzheimer or other listed diseases. The patient populations in each pathological condition are also very distinct. The health status, the medication, the diagnosis, and the physiological condition in patients with prion disease are very different from those with Alzheimer or other listed diseases. It requires different diagnoses, equipments, steps and treatments for these different groups of patients. Therefore, these species do not share a common corresponding technical feature; and thus lack unity of invention.

4. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be

traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated Groups I-VII and a single species from groups i-iv that are applicable as set forth above to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected group and species.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday and every other Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Christine J Saoud/
Primary Examiner, Art Unit 1647

/CYW/
Chang-Yu Wang, Ph.D.
June 26, 2008